

WHAT IS CLAIMED

- add 22
1. As a tissue supporting device a constrainable, self-expanding member of generally tubular shape comprised of first and second portions; first portion being of a resilient material; the second portion being of a deformable and substantially less resilient material than the first portion; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the device being self-expanding when unconstrained to an initially deployed diameter due to the resiliency of the first portion; the portions being so associated with respect to each other and the member such that the device may be further deformed due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.
  2. The device of claim 1 wherein the first and second portions are of metal.
  3. The device of claim 2 wherein the first portion is a spring metal and the second portion is an annealed metal.
  4. The device of claim 1 wherein the first and second portions are in the form of layers.
  5. The device of claim 1 wherein the first and second portions are discrete portions in the circumference of the device body.
  6. The device of claim 1 wherein the first and second portions are of shape memory alloy, austenite and martensite, respectively.
  7. The device of claim 1 wherein the first and second portions are strands.
  8. The device of claim 1 wherein the first and second portions are of a shape memory alloy.
  9. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter comprised, at about normal body temperatures, of a shape-memory, superelastic, austenitic alloy portion and a shape memory, martensitic alloy portion, the superelastic austenitic alloy portion having a transition temperature from martensitic to austenitic less than body temperature while the martensitic alloy portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensitic alloy portion and superelastic austenitic alloy

portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the austenitic alloy portion to martensitic at a temperature below the transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenitic superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the martensitic alloy portion whereby the austenitic alloy portion can be deformed by external force without plastic deformation along with the martensitic portion to an enlarged stent diameter beyond that of the self-expanded diameter.

10. The stent of claim 9 wherein the first and second portions are in the form of layers in overlying relationship.

11. The stent of claim 9 wherein the first and second portions are different phases in an alloy.

12. The stent of claim 9 wherein the first and second portions are in the form of strands.

13. The stent of claim 9 wherein the first and second portions are in the form of longitudinally arranged interconnected alternating rings.

14. The stent of claim 9 comprised of a plurality of cable-like strands and wherein each strand is comprised of a plurality of wires some of which are of the first portion and some of which are of the second portion.

15. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory, martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature while the martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion and superelastic austenite phase portion being constructed, arranged and associated with

09427291 102699

respect to each other in comprising the stent such that the two portions act in combination to allow, upon transformation of the austenite phase portion to martensite, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back toward the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to the fabricated diameter parent shape due to its shape memory but being restrained therefrom by the martensite portion whereby the austenite portion recovery back toward the fabricated diameter can be assisted by external force along with the deforming of the martensitic portion without slip deformation to an enlarged stent diameter beyond that of the restrained self-expanded diameter.

16. As a tissue supporting device, a constrainable, self-expanding member of generally tubular shape comprised of first and second portions of nickel-titanium shape-memory alloy; the first portion alloy having martensitic and austenitic superelastic shape memory metallurgical states and a transition temperature therebetween, the transition temperature being at less than body temperature; the second portion alloy having martensitic and austenitic metallurgical states and a transition temperature therebetween, the transition temperature being substantially higher than body temperature, said first portion alloy being transformable from austenitic to the martensitic state when cooled below its transition temperature so as to render both alloy portions in the martensitic state whereby the member is constrainable to a deployable diameter in preparation for insertion into a patient, during which the first portion alloy may transform to the austenitic state while constrained, the second portion alloy being and remaining in the martensitic state; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to the first portion alloy being in the austenitic state and the second portion alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the second portion alloy restrains the first portion so that the member assumed the initially deployed diameter, because of the restriction of the austenitic superelastic alloy from the full

exercise of its shape memory and whereby the alloy portions may be further deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

17. A self-expanding stent comprised of at least two components arranged for coaction, the first component being substantially austenite and the second being substantially martensite.

18. The stent of claim 16 wherein the first component is a nitinol alloy.

19. The stent of claim 16 wherein the first component is superelastic and the second component is any deformable material.

20. As a tissue supporting device, a constrainable, self-expanding member of generally tubular shape comprised of nickel-titanium shape memory alloy containing components of both martensite and austenite phases, the transition temperature being at about body temperature, said alloy being transformable to the fully martensitic state when cooled below its transition temperature so as to render it to the martensitic state whereby the member is more easily constrainable to a deployable diameter in preparation for insertion into a patient; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to a portion of the alloy being in the austenitic state and a portion of the alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the member assumes the initially deployed diameter, upon self-expansion and the alloy portions may be further deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

21. A permanent self expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature while martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion and superelastic austenite phase portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two portions act

independently to allow, upon transformation of the austenite phase portion to martensite, constraint of both of the original phase portions of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back to the austenite phase portion predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the austenitic portions of the stent to the fabricated diameter parent shape due to its shape memory, with the martensitic portions remaining in the deployment shape, additional recovery back toward the stent fabricated diameter parent shape can be assisted by an external force deforming the martensitic portion without slip deformation to an enlarged stent diameter beyond that of the self-expanded austenitic portion diameter, but not greater than the stent fabricated diameter parent shape.

15

F:\WPWORK\OFA\5519-APP.511

09427291-10669  
66920T "T6272460